Section 3. 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax Number of the Applicant

EKOM s.r.o
Priemyselna 5031/18
921 01 Piestany
Slovak Republic
Tel: +421 33 7967255
Fax: +421 33 7967223

B. Contact Person

Julius Ivan
EKOM s.r.o
Priemyselna 5031/18
921 01 Piestany
Slovak Republic

C. Date Prepared

March 3, 2006

D. Device Name

Medical Compressors DK50 D and DK50 DM

E. Device Description

The DK50 D and DK50 DM Medical Compressors are electric and produces air from the normal environment to supply compressed air for medical ventilators.

F. Device Intended Use

The DK50 D and DK50 DM Medical Compressors are indicated for supplying compressed air for medical ventilators.

G. Substantial Equivalence Summary

The DK50 D and DK50 DM Medical Compressors are substantially equivalent in intended use, physical characteristics, performance, and safety characteristics to the Newport C250 Air Compressor, cleared under #K041406.

H. Device Testing

Comprehensive testing has been conducted on The DK50 D and DK50 DM Medical Compressors in accordance with various industry recognized standards, including: IEC 60601-1-2:2001, EN 55011:1998 &A1:1999. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2006

Ekom S.R.O.
C/O Ms. Esther Saltz
Esther Saltz Regulatory Consulting
32884 Danapoplar
Dana Point, California 92629

Re: K060781
Trade/Device Name: Medical Compressor, Models DK50 D and DK50 DM
Regulation Number: 21 CFR 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: II
Product Code: BTI
Dated: September 11, 2006
Received: September 13, 2006

Dear Ms. Saltz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix A. Indications for Use

510(k) Number (if known): _____

Device Name: The Medical Compressor Models DK50 D and DK50 DM

Indications for Use:

The DK50 D and DK50 DM Medical Compressors are indicated for supplying compressed air for medical ventilators.

Prescription Use ____√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

Amy Sullivan

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K060781